HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
MAIDEN

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

November 4, 1998 WL-6-9

Betty A. Robinson
Myron L. Company
6115 Corte del Cedro
Carlsbad, CA 92009

Dear Ms. Robinson:

We are writing to you because during an inspection of your firm conducted between August 28 to September 10, 1998, our investigator determined that your firm manufactures and distributes "Ultrameters" for water analysis. Labeling for the product (promotional materials) contains claims that these instruments intended uses include water testing for ultra-pure water controls of medical instruments for artificial kidney machines.

Under the United States Federal law, this product is considered to be a medical device as that term is defined by section 201(h) Federal Food and Cosmetic Act (the Act). The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that your firm obtained marketing clearance before offering the product for sale. You may obtain premarket application information from the Center for Devices and Radiological Health (CDRH) Division of Small Manufacturers Assistance (DSMA) at the following address:

Center for Devices and Radiological Health
Division of Small Manufacturers (DSMA)
HFZ-220
1350 Piccard Drive
Rockville, MD 20850

Additionally, the information necessary to comply with the Premarket Notification [510(k)] requirement is found in 21 CFR, Part 807, Subpart E - Premarket Notification Procedures.

Because your firm does not have marketing clearance from FDA, marketing this device is a violation of the law. In legal terms, the device is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows the device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, injunction, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts or approving requests for Certificates to Foreign Governments for Export.

It is necessary for you to take action on this matter. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this form happening again. If you need more time, state the reason for the delay and the time within which the corrections will be completed. Additionally, please advise us of any action you have taken or plan take to address the previously distributed product.

Please submit your response to :

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, California 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issues of premarket clearance and radiological health and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting DSMA at phone number: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website at http://www.fda.gov/cdrh

Sincerely yours,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th St. MS-357
P.O. Box 942732
Sacramento, CA 94234